

LABEL IN PART: (Ctn. and sleeve of 56-ctn. lot) "Gladiator 3 pack reservoir end * * * Prophylactics"; (can of 138-ctn. lot) "Sold for the prevention of disease only Gladiator transparent thins"; and (ctn. and sleeve of 198-ctn. lot) "Checks Deluxe Thin Prophylactics."

RESULTS OF INVESTIGATION: Examination revealed that 3 out of 96 units of the article in the 56-ctn. lot, 3 out of 144 units of the article in the 138-ctn. lot, and 3 out of 150 units of the article in the 198-ctn. lot contained holes.

LIBELED: 4-29-60, E. Dist. N.Y.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported and was represented to possess; 502(a)—the label statements "Prophylactics" (56-ctn. and 198-ctn. lots) and "Sold for the prevention of disease only" (138-ctn. lot) were false and misleading as applied to a product which contained holes.

DISPOSITION: 6-23-60. Consent—claimed by the shipper and destroyed.

DRUGS AND DEVICE ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

6492. Safflower seed oil, soy oil, vitamin B₂ tablets, vitamin A capsules, V-Complete multivitamin and mineral tablets, Super Potency multivitamin and mineral tablets, Liverall tablets, vitamin C, vitamin B complex tablets, brewer's yeast powder and tablets, wheat germ cereal, flaked yeast, sunflower seeds. (F.D.C. No. 45016. S. Nos. 8-481/3 R, 8-485/95 R.)

QUANTITY: 1 150-lb. drum, and 3 qt. btls., 21 pt. btls., and 3 gal. containers, of safflower seed oil; 50 qt. btls., 57 pt. btls., and 6 gal. btls., of soy oil; 17 100-tablet btls. of vitamin B₂; 1 100-capsule btl., and 5 250-capsule btls. of vitamin A; 4 300-tablet btls., 6 100-tablet btls., and 7 60-tablet btls., of V-Complete multivitamins and minerals; 11 300-tablet btls., 2 100-tablet btls., and 6 60-tablet btls., of Liverall; 4 4-lb. jars, and 11 1-lb. jars, of brewer's yeast; 11 1,000-tablet btls. of brewer's yeast; 47 100-tablet btls. of Super Potency multivitamin and minerals; 22 100/100 mg. btls., 15 250/100 mg. btls., 5 500/100 mg. btls., 1 250/200 mg. btl., and 5 500/250 mg. btls., of vitamin C; 3 100-tablet btls., 17 250-tablet btls., and 6 500-tablet btls., of vitamin B complex; 5 ctns., 12 9-oz. pkgs. each, of wheat germ cereal; 148 1-lb. bags of flaked yeast; and 120 12-oz. jars, 134 1-lb. packs, and 4 50-lb. bags, of sunflower seeds, at Rochester, N.Y., in possession of Niblack Foods, operating a retail outlet under the name of Dietary Specialties.

SHIPPED: Between the approximate dates of 12-31-58 and 8-3-60, from various places outside the State of New York.

LABEL IN PART: (Btls.) "Niblack's Safflower Seed Oil 92% Unsaturated Fatty Acids Contents * * * Packed by Niblack Foods, Rochester 8, N.Y.," "Niblack's Soy Oil Contents * * * Niblack Foods, Rochester 8, N.Y.," "Thompson's Standardized Vitamins Vitamin B₂ 10 Milligrams HH 2579 Each tablet contains 10 Milligrams of Riboflavin (Vitamin B₂)," "Thompson's Standardized Vitamins Vitamin A 20,000 U.S.P. Units Per Tablet #13328," "V-Complete Natural Vitamins Natural Minerals Organic Iron+B₁₂ * * * A Food Supplement Providing an Excellent Source of Food Derived Vitamins and Minerals Skillfully Combined with an Organic Iron Compound," and "Schiff Natural Liverall Desiccated Low Heat Dried Liver"; (jar) "Schiff

*See also Nos. 6485-6487, 6489-6491.

Brewer's Yeast U.S.P. Fortified with A.P.F. Vitamin B-12 Natural B Complex Protein"; (btls.) "Brewer's Yeast U.S.P. Grade A good source of protein (50%) and vitamin B Complex natural to non-fermenting U.S.P. Dried Brewer's Yeast," "Super Potency Natural & Organic Vitamins and Minerals A Natural Food Supplement with Vitamin B-12 and Organic Iron. * * * Distributed by Niblack Foods, 20 Magnolia Street, Rochester 8, New York 42679," Thompson's Standardized Vitamins Vitamin C * * * 2,000 U.S.P. Units Each," and "Thompson's Standardized Vitamins Vitamin B Complex Special High Potency All Important B-Complex Vitamins in a Natural Base"; (pkg.) "Battle Creek Protein-Rich . . . Ready to Eat! Wheat Germ Plus Other Parts of Wheat Flakes A Delicious New Hi-Nourishment Cereal! Ingredients—Wheat Germ, Other Parts of Wheat, Sugar Molasses and Salt"; (bag) "Flaked Yeast 1 Lb."; and (jar) "Niblack's Vacuum Packed Hulled Sunflower Seeds Raw Packed by Niblack Foods, Rochester 8, New York."

ACCOMPANYING LABELING: Reprints of the following articles from "Health Saver National Consumer Health Food Magazine," all by Roland Evin Horvath, Editor: "Cancer in Your Foods," "How to Protect Your Heart," "Don't Let Headaches Afflict You!," "End Your Sinus Trouble!," "Healthy Eyesight and Vitamins," and "Key to Vibrant Health Sunflower Seeds."

RESULTS OF INVESTIGATION: The above-mentioned *safflower seed oil* in the quart and pint bottles and in the gallon containers, the *soy oil*, the *Super Potency multivitamin and mineral tablets*, the *flaked yeast*, and the *sunflower seeds*, were repacked by the dealer from bulk lots shipped as described above.

LIBELED: 10-19-60, W. Dist. N.Y.

CHARGE: *Safflower seed oil* and *soy oil*. 502(a)—while held for sale, the accompanying labeling of the articles, consisting of the reprint entitled "How to Protect Your Heart," contained false and misleading representations that the articles were adequate and effective as a treatment to prevent heart disease, cholesterol deposits in the arteries, heart attack, cerebral hemorrhage, clogged arteries, angina pectoris, and arteriosclerosis.

Vitamin B₂ tablets. 502(a)—while held for sale, the accompanying labeling of the article, consisting of the reprint entitled "Healthy Eyesight and Vitamins," contained false and misleading representations that the article was adequate and effective as a treatment for and preventive of bloodshot eyes; dimming vision; burning eyeballs; eye weakness and excessive watering; cataracts; premature aging; dark, lumpy pouches around eyes; spots before eyes; eye aches; extreme sensitivity to ordinary light; sandlike roughness beneath eyelids; eyestrain causing headaches, nervousness, general fatigue, faulty digestion, sleeplessness, inability to concentrate, general inefficiency; and to prevent serious eye infections.

Vitamin A tablets. 502(a)—while held for sale, the accompanying labeling of the article, consisting of reprints entitled "End Your Sinus Trouble" and "Healthy Eyesight and Vitamins," contained false and misleading representations that the article was adequate and effective as a treatment for and preventive of sinus trouble; bloodshot eyes; dimming vision; burning eyeballs; eye weakness and excessive watering; cataracts; premature aging; dark, lumpy pouches under eyes; spots before eyes; eye aches; eye strain causing headaches, nervousness, general fatigue, faulty digestion, sleepless-

ness, inability to concentrate, and general inefficiency; harmful consequences to the eyes due to viewing television; and to keep eyes normal, healthy, and sparkling.

V-Complete multivitamin and mineral tablets and Super Potency multivitamin and mineral tablets. 502(a)—while held for sale, the accompanying labeling of the articles, consisting of the reprint entitled "How to Protect Your Heart," contained false and misleading representations that the articles were adequate and effective as a treatment for and preventive of heart disease, atherosclerosis, heart attack, cerebral hemorrhage, clogged arteries, angina pectoris, and arteriosclerosis.

Liverall tablets. 502(a)—while held for sale, the accompanying labeling of the article, consisting of the reprint entitled "Cancer in Your Foods," contained false and misleading representations that the article was adequate and effective as a preventive of cancer; that vitamin B₁₂ and folic acid have a protective effect on the liver and speed recovery from viral hepatitis (liver infection); that kelp and honey are adequate and effective as a treatment for and preventive of muscle weakness, diminished tendon reflexes, serious electrocardiogram changes; and that liver cancer occurrence is associated with the lack of adequate proteins and vitamins and cirrhosis of the liver.

Vitamin C tablets. 502(a)—while held for sale, the accompanying labeling of the article, consisting of reprints entitled "Cancer in Your Foods" and "End Your Sinus Trouble," contained false and misleading representations that the article was adequate and effective as a preventive of cancer; as a treatment for and preventive of sinus trouble, aches and pains of sinus infection, and to build resistance to bacterial invasions which result in sinus trouble; that vitamin B₁₂ and folic acid have a protective effect on the liver and speed recovery from viral hepatitis (liver infection); that kelp and honey are adequate and effective as a treatment for and preventive of muscle weakness, diminished tendon reflexes, serious electrocardiogram changes; and that liver cancer occurrence is associated with the lack of adequate proteins and vitamins and cirrhosis of the liver.

Vitamin B complex tablets. 502(a)—while held for sale, the accompanying labeling of the article, consisting of reprints entitled "Cancer in Your Foods," "How to Protect Your Heart," and "Don't Let Headaches Afflict You!," contained false and misleading representations that the article was adequate and effective as a preventive of cancer; as a treatment for and preventive of heart disease, atherosclerosis, heart attack, and cerebral hemorrhage, headaches, jangled nerves, irritability, nervousness, fatigue, feeling of depression, muscle and joint pains, lassitude, inefficiency, emotional stress and strain, poor appetite, irregular bowel movements to severe constipation, quarrelsomeness, and jumpiness; that vitamin B₁₂ and folic acid have a protective effect on the liver and speed recovery from viral hepatitis (liver infection); that kelp and honey, in view of their content of potassium, are adequate and effective as a treatment for and preventive of muscle weakness, diminished tendon reflexes, serious electrocardiogram changes; and that liver cancer occurrence is associated with the lack of adequate proteins and vitamins and cirrhosis of the liver.

Brewer's yeast powder and tablets. 502(a)—while held for sale, and accompanying labeling of the articles, consisting of reprints entitled "Cancer in Your Foods" and "Don't Let Headaches Afflict You!," contained false and misleading representations that the articles were adequate and effective as a preventive of cancer; as a treatment for and preventive of headaches, jangled

nerves, irritability, nervousness, fatigue, feeling of depression, muscle and joint pains, lassitude, inefficiency, emotional stress and strain, poor appetite, irregular bowel movements to severe constipation, quarrelsomeness, and jumpiness; that vitamin B₁₂ and folic acid have a protective effect on the liver and speed recovery from viral hepatitis (liver infection); that kelp and honey are adequate and effective as a treatment for and preventive of muscle weakness, diminished tendon reflexes, serious electrocardiogram changes; and that liver cancer occurrence is associated with the lack of adequate proteins and vitamins and cirrhosis of the liver.

Wheat germ cereal. 502(a)—while held for sale, the accompanying labeling of the article, consisting of the reprint entitled "Cancer in Your Foods," contained false and misleading representations that the article was adequate and effective as a preventive of cancer; that vitamin B₁₂ and folic acid have a protective effect on the liver and speed recovery from viral hepatitis (liver infection); that kelp and honey are adequate and effective as a treatment for and preventive of muscle weakness, diminished tendon reflexes, serious electrocardiogram changes; and that liver cancer occurrence is associated with the lack of adequate proteins and vitamins and cirrhosis of the liver.

Flaked yeast. 502(a)—while held for sale, the accompanying labeling of the article, consisting of reprints entitled "Cancer in Your Foods" and "Don't Let Headaches Afflict You!," contained false and misleading representations that the article was adequate and effective as a preventive of cancer; and as a treatment for and preventive of headaches, jangled nerves, irritability, nervousness, fatigue, feeling of depression, muscle and joint pains, lassitude, inefficiency, emotional stress and strain, poor appetite, irregular bowel movements to severe constipation, quarrelsomeness, and jumpiness; that vitamin B₁₂ and folic acid have a protective effect on the liver and speed recovery from viral hepatitis (liver infection); that kelp and honey are adequate and effective as a treatment for and preventive of muscle weakness, diminished tendon reflexes, serious electrocardiogram changes; and that liver cancer occurrence is associated with the lack of adequate proteins and vitamins and cirrhosis of the liver.

Sunflower seeds. 502(a)—while held for sale, the accompanying labeling of the article, consisting of the reprint entitled "Key to Vibrant Health Sunflower Seeds," contained false and misleading representations that the article was adequate and effective as a treatment for and preventive of pellagra, improper skin, digestive, and nervous systems, heart conditions, heart trouble, heart attack, atherosclerosis, to control and reduce the cholesterol level of the blood, prevent sterility, reduce and eliminate body wastes, and build sound bones and teeth, activate and regulate enzymes, for proper fat and carbohydrate digestion, to build good muscle and tissue tone, promote proper nerves and clotting of blood, healthy, red blood corpuscles, hard tooth enamel, maintain the natural fluidity of the blood, promote normal growth and metabolism, appetite, proper nerve functioning, good mobility and tone of stomach and intestines, proper digestion, healthy skin, and increase endurance.

The libel alleged also that the *flaked yeast* and the *sunflower seeds* were misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 12-5-60. Consent—claimed by Everett J. Niblack, t/a Dietary Specialties, and relabeled.